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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,602	04/18/2001	Axel R. Zander	35-204	8963

7590 11/05/2002

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/05/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/836,602

Applicant(s)

ZANDER, AXEL R.

Examiner

Gerald G Leffers Jr.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23, 26-29 and 31-34 is/are pending in the application.
- 4a) Of the above claim(s) 12-23, 26-29 and 31-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-11 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 9. 6) ☐ Other: \_\_\_\_\_

Art Unit: 1636

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-11) in Paper No. 12, filed 8/19/02, is acknowledged.

Claims 12-23, 26-29, 31-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Objections***

Claims 1-11 are objected to because of the following informalities: each of the claims lacks an article (e.g. "A" or "The"). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Art Unit: 1636

The rejected claims are drawn towards a host cell transduced with a vector comprising a gene transfer vector of the invention, including human cells. The specification teaches the vectors of the invention can be used to transduce human cells in vivo (e.g. for gene therapy applications). The claims thus can be reasonably interpreted to encompass cells within a human. Therefore, the claims can be interpreted to read upon a human, which is non-statutory subject matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-9, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcia-Hernandez et al (Molecular Medicine, 1996, Vol. 2, No. 1, pages 125-133; see the entire document).

The rejected claims encompass sequences encoding “mutants” or “variants” of cd34 that are expressed as cell surface markers. Given the broad definitions of these terms given in the instant specification (e.g. page 4, second paragraph), these terms can be reasonably read to encompass any change in the cd34 sequence that encodes a protein that can be used as a cell surface marker.

Garcia-Hernandez et al teach a retroviral vector that comprises a transgene (an antisense-coding sequence directed towards BCR-ABLp190) and a cell surface marker for selection of transduced cells (CD5) (e.g. Abstract).

Claims 1-4, 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Leonard et al (BLOOD, 1996, vol. 88, No. 10, Suppl. 1, part 1-2, page 443A, XP001013590; see the entire abstract).

The rejected claims encompass sequences encoding "mutants" or "variants" of cd34 that are expressed as cell surface markers. Given the broad definitions of these terms given in the instant specification (e.g. page 4, second paragraph), these terms can be reasonably read to encompass any change in the cd34 sequence that encodes a protein that can be used as a cell surface marker.

Leonard et al teach the use of a retroviral vector comprising a sequence encoding a cell surface marker (LNGFR) to optimize transgene expression in transduced human cells.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1636

Claim 6 is drawn towards a particular vector (DSM 13396) Because it is not clear that the identical vector is freely available or can be reproducibly isolated from nature a biological deposit for patenting purposes is required.

It is noted that the specification indicates that a deposit has been made and that a statement regarding viability of the deposit was filed with the instant specification. However, there is no statement from applicant or applicant's representative concerning availability of the deposited material upon issuance of the rejected claim. Such a statement that all restrictions on the deposited material will be removed upon allowance of the rejected claim is required.

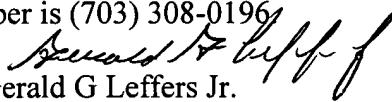
***Conclusion***

No claims are allowed. Claim 5 is objected to as being dependent upon a rejected claim but would be allowable if rewritten with all of the limitations of the claim upon which it is currently dependent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Gerald G Leffers Jr.  
Examiner  
Art Unit 1636

ggl  
November 4, 2002